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5. 510(k) Summary

5.1 Description

Dimension® Creatinine (CRE2) Flex® reagent cartridge

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

5.2. Assigned 510(k) number

The assigned 510(k) number is: K132638

5.3 Applicant and Date

Applicant: Laura J. Duggan
Siemens Healthcare Diagnostics Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date: August 22, 2013

5.4 Proprietary and Established Names

Dimension® Creatinine (CRE2) Flex® reagent cartridge

Common Name

Creatinine

5.5 Regulatory Information

Dimension® Creatinine (CRE2) Flex® reagent cartridge

The CRE2 method is an *in vitro* diagnostic test for the quantitative measurement of creatinine in human serum, plasma, and urine on the Dimension® clinical chemistry system. Creatinine measurements are used in the diagnosis and treatment of certain renal disease, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Classification Name:	Creatinine test system
Regulation Section:	21CFR862.1225 – Creatinine test system
Classification:	Class II
Product Code:	CGX
Panel:	Clinical Chemistry

5.6 Predicate Device

The predicate device used to demonstrate substantial equivalence to the Dimension® Creatinine (CRE2) Flex® reagent cartridge is the Creatinine Method for Use on the Dimension® Clinical Chemistry System (CREA) previously cleared under k925668.

5.7 Device Description / Test Principle

The CRE2 method uses a modified kinetic Jaffe technique. In the presence of a strong base such as sodium hydroxide, picrate reacts with creatinine to form a red chromophore. The rate of increasing absorbance at 510 nm due to the formation of this chromophore is directly proportional to the creatinine concentration in the sample and is measured using a bichromatic (510, 600nm) rate technique. Bilirubin is oxidized by potassium ferricyanide to prevent interference.

5.8 Intended Use

The CRE2 method is an *in vitro* diagnostic test for the quantitative measurement of creatinine in human serum, plasma, and urine on the Dimension® clinical chemistry system. Creatinine measurements are used in the diagnosis and treatment of certain renal disease, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

5.9 Indication(s) for Use

The CRE2 method is an *in vitro* diagnostic test for the quantitative measurement of creatinine in human serum, plasma, and urine on the Dimension® clinical chemistry system. Creatinine measurements are used in the diagnosis and treatment of certain renal disease, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

5.10 Substantial Equivalence Information

Both the Dimension® Creatinine (CRE2) Flex® reagent cartridge and the predicate Creatinine Method for Use on the Dimension® Clinical Chemistry System (CREA) employ prepackaged reagents for use on automated clinical chemistry test systems. A comparison of the similarities and differences between the devices is provided in the following tables:

Similarities for the Dimension® Creatinine (CRE2) Flex® reagent cartridge:

	New Device	Predicate Device
Feature	**Dimension® Creatinine (CRE2) Flex® reagent cartridge (K132638)**	**Creatinine Method for Use on the Dimension® Clinical Chemistry System (CREA) (k925668)**
Intended Use	The CRE2 method is an *in vitro* diagnostic test for the quantitative measurement of creatinine in human serum, plasma, and urine on the Dimension® clinical chemistry system. Creatinine measurements are used in the diagnosis and treatment of certain renal disease, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.	The CREA method used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of creatinine in human serum, plasma and urine.
Device Technology (detection)	Modified Jaffe Methodology (creatinine alkaline picrate) with photometric detection	Same
Detection Conditions	Wavelength = 510 and 600 nm Type of Measurement = Bichromatic rate	Same
Sample Volume	20 µL	Same
Reagents	Reagent 1 = Lithium Picrate (125 mM) Reagent 2 = Sodium Hydroxide (2000 mM) with potassium ferricyanide (2.7 mM)	Same
Reagent Volumes	Volume of Reagent 1 used = 74 µL Volume of Reagent 2 used = 18 µL Volume of Diluent used = 258 µL	Same
Calibration Interval	90 days - same reagent lot	Same

Limit of Blank/Analytical Sensitivity	Limit of Blank: 0.05 mg/dL	Analytical Sensitivity : 0.05 mg/dL
Calibration	Chem 1 Calibrator (K860021) 3 levels (n=3)	Same (K860021)

Differences for the Dimension® Creatinine CRE2 Flex® reagent cartridge:

	New Device	**Predicate Device**
Feature	**Dimension® Creatinine (CRE2) Flex® reagent cartridge (K132638)**	**Creatinine Method for Use on the Dimension® Clinical Chemistry System (CREA) (k925668)**
Measuring Range (serum)	0.15 - 20.00 mg/dL	0 – 20.0 mg/dL
Measuring Range (urine)	5.00 – 400.00 mg/dL	0 – 200.0 mg/dL
Expected Values	Serum and Plasma Males: 0.70 – 1.30 mg/dL Females: 0.55 – 1.02 mg/dL Urine Males: 0.95 – 2.49 g/24 hr Females: 0.60 – 1.80 g/24 hr	Serum Males: 0.8 – 1.3 mg/dL Females: 0.6 – 1.0 mg/ Urine Males: 0.6 – 2.5 g/24 hr Females: 0.6 – 1.5 g/24 hr
Interferences	No significant interference at a Creatinine concentration of 1.5 mg/dL from: Hemoglobin at 500 mg/dL Bilirubin (conjugated) at 20 mg/dL, Bilirubin (unconjugated) at 10 mg/dL Lipemia (Intralipid) at 1000 mg/dL.	No significant interference at a Creatinine concentration of 1.7 mg/dL from: Hemoglobin at 1000 mg/dL, Bilirubin (unconjugated) at 5 mg/dL Lipemia (Intralipid) at 200 mg/dL

5.11 Standard/Guidance Document Reference

- Stability Testing of In Vitro Diagnostic Reagents (CEN 13640)
- CLSI EP07-A2; Interference Testing in Clinical Chemistry; Approved Guideline
- CLSI EP09-A2-IR; Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline
- CLSI EP05-A2; Evaluation of Precision Performance of Quantitative Measurement Methods: Approved Guideline
- CLSI EP06-A; Evaluation of the Linearity of Quantitative Measurement
- CLSI EP17-A2; Protocols for Determination of Limits of Detection and Limits of Quantitation
- CLSI C28-A3c; Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline - Third Edition
- In Vitro Diagnostic Creatinine Test System - Guidance for Industry - July 2, 1998
- In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions – Jan. 1997
- Format for Traditional and Abbreviated 510(k)'s – Guidance for Industry and Staff – Nov. 17, 2005
- Guidance for Industry and FDA Staff: Administrative Procedures for CLIA Categorization – May 7, 2008
- eCopy Program for Medical Device Submissions - Guidance for Industry and Food and Drug Administration Staff – December 31, 2012.
- Refuse to Accept Policy for 510(k)s - Guidance for Industry and Food and Drug Administration Staff – December 31, 2012

5.12 Performance Characteristics

The following data represent typical method performance. These data were collected on the Dimension EXL 200 integrated chemistry system.

5.12.1 Method Comparison

The predicate device selected for the method comparison was the Creatinine Method for Use on the Dimension® Clinical Chemistry System (CREA) cleared under K925668. Remnant de-identified serum samples were tested. No patient history information was obtained on these samples. Inclusion/exclusion data criteria are not applicable. All of the samples were native.

These studies were conducted internally by Siemens Healthcare Diagnostic Inc. R&D organization personnel. The personnel conducting the study were laboratory technicians with training similar to personnel who would conduct the tests in a hospital laboratory setting. They were trained on the operation of both the device and the predicate device. A split sample method comparison, following EP09-A2, demonstrated good agreement between the Dimension® Creatinine (CRE2) Flex® reagent cartridge and the predicate Creatinine Method for Use on the Dimension® Clinical Chemistry System (CREA) with serum patient samples.

One hundred ninety one serum patient samples across the assay range were tested on the Dimension® Creatinine (CRE2) Flex® reagent cartridge and the Creatinine Method for Use on the Dimension® Clinical Chemistry System (CREA). In a second study, 113 urine samples were tested on the Dimension® Creatinine (CRE2) Flex® reagent cartridge and the Creatinine Method for Use on the Dimension® Clinical Chemistry System (CREA). The results across the full assay range were analyzed by linear regression. Although the samples were tested in duplicate, only the first result was used for the analysis.

Comparative Method	Range (mg/dL)	Slope	Intercept (mg/dL)	Correlation Coefficient	n	Sample type
Dimension CREA Assay	0.4 – 19.8	1.00	-0.08	0.999	191	serum
Dimension CREA Assay	13.5 – 372.7	1.04	-3.58	0.996	113	urine

The model equation for the regression statistics is: [results for Dimension® CRE2 Flex® reagent cartridge] = slope x [comparative method results] + intercept.

An additional study was completed comparing the Dimension® Creatinine (CRE2) Flex® reagent cartridge for the IDMS reference method. Remnant de-identified serum samples were tested. No patient history information was obtained on these samples. Inclusion/exclusion data criteria are not applicable. All of the samples were native.

Forty eight patient samples were tested on the Dimension® Creatinine (CRE2) Flex® reagent cartridge and the IDMS reference method. The results were analyzed by linear regression. Although the samples were tested in duplicate, only the first result was used for the analysis.

Comparative Method	Range (mg/dL)	Slope	Intercept (mg/dL)	Correlation Coefficient	n	Sample type
IDMS Reference Method	0.18– 6.32	1.04	0.02	0.997	48	serum

The model equation for the regression statistics is: [results for Dimension® Creatinine (CRE2) Flex® reagent cartridge] = slope x [comparative method results] + intercept.

5.12.2 Serum Plasma Equivalency

Serum and lithium heparin plasma equivalency was demonstrated for the Dimension® Creatinine (CRE2) Flex® reagent cartridge. Fifty six matched serum and lithium heparin plasma samples were tested using the Dimension® Creatinine (CRE2) Flex® reagent cartridge. The table below summarizes the linear regression statistics.

Serum vs.	Slope	Intercept	Correlation Coefficient (r)	Range	n
Lithium Heparin Plasma	1.05	-0.02	0.998	0.50 – 17.35	56

One replicate of each sample was processed. All samples in the study were fresh and never frozen. The eight spiked sample sets were prepared by spiking equal amounts of purified creatinine into the matched serum and lithium heparin plasma samples.

5.12.3 Precision

Precision testing was performed in accordance with CLSI EP05-A2 Evaluation of Precision Performance of Quantitative Measurement Methods: Approved Guideline – Second Edition. Samples consisted of two (2) serum pools, three (3) levels of BioRad Multiqual material, two (levels) of BioRad Liquicheck material and two (2) urine pools. Testing was performed over twenty (20) days, two (2) separate runs with two test samples for each test material. Analysis of variance (ANOVA) was used to evaluate the data consistent with the recommendations of EP05-A2. The data are summarized in the following table:

			Repeatability		Within-Lab	
Sample		Mean (mg/dL)	SD	%CV	SD	%CV
Serum	Serum Pool 1	1.32	0.04	3.0	0.04	3.2
	Serum Pool 2	15.79	0.19	1.2	0.19	1.2
	BioRad Multiqual Level 1	0.71	0.03	4.7	0.04	5.1
	BioRad Multiqual Level 2	1.79	0.04	2.1	0.05	2.8
	BioRad Multiqual Level 3	7.04	0.07	1.0	0.09	1.3
Urine	Urine Pool 1	39.31	1.52	3.9	1.53	3.9
	Urine Pool 2	339.56	4.28	1.3	4.59	1.4
	BioRad Liquicheck Level 1	62.28	0.61	1.0	1.41	2.3
	BioRad Liquicheck Level 2	142.80	1.56	1.1	3.39	2.4

5.12.4 Limit of Blank and Limit of Detection

The Limit of Blank (LoB) and Limit of Detection (LoD) were evaluated in accordance with CLSI EP17-A2 Protocols for Determination of Limits of Detection and Limits of Quantitation: Approved Guideline.

Dimension® Creatinine (CRE2) Flex® reagent cartridge Limit of Detection Results with Serum		
Limit	Protocol	Value
LoB	4 samples with no analyte were tested (N=5) for 3 days, one run per day, 2 reagent lots,	0.05 mg/dL
LoD	4 low patient serum samples were tested (N=5) for 3 days, one run per day, 2 reagent lots	0.1 mg/dL

Dimension® Creatinine (CRE2) Flex® reagent cartridge Limit of Detection Results with Urine		
Limit	Protocol	Value
LoB	4 samples with no analyte were tested (N=5) for 3 days, one run per day, 2 reagent lots,	1.0 mg/dL
LoD	4 low patient urine samples were tested (N=5) for 3 days, one run per day, 2 reagent lots	2.0 mg/dL

The nonparametric approach described in EP-17A2 was followed to determine the Limit of Detection.

LoB = Mean of Blank Measurement + 1.645 x Standard Deviation of Blank Measurements
LoD = Limit of Blank + C_pSD_s

- C_p is a correction factor for the 95% CI normal variate to account for bias in the SD_S estimate.
- SD_S is an estimate of method imprecision pooled from replicates of the low analyte samples

The LoB was determined to be 0.05 mg/dL with serum samples and is consistent with the claim of 0.05 mg/dL. With urine samples, the LoB was determined to be 0.87 mg/dL and is consistent with the claim of 1.0 mg/dL.

The LoD was determined to be 0.08 mg/dL with serum samples and is consistent with the claim of 0.1 mg/dL. With urine samples, the LoD was determined to be 1.51 mg/dL and is consistent with the claim of 2.0 mg/dL.

5.12.5 Limit of Quantitation

The Limit of Quantitation (LoQ) for the Dimension® Creatinine (CRE2) Flex® reagent cartridge for serum and plasma is 0.15 mg/dL and based on allowable total error of 0.15 mg/dL, determined consistent with CLSI Guideline EP17-A2.

The Limit of Quantitation (LoQ) for the Dimension® Creatinine (CRE2) Flex® reagent cartridge for urine is 5.00 mg/dL and based on allowable total error of 3.00 mg/dL, determined consistent with CLSI Guideline EP17-A2.

5.12.6 Linearity (Measurement Range)

Linearity was evaluated for serum and urine samples by using 12 equally spaced samples which spanned the assay range. Each was prepared by mixing high and low creatinine concentration samples across the measurement range as described in CLSI Evaluation of the Linearity of Quantitative Measurement Procedure (EP06-A).

Regression Statistics

Range of samples	Slope	Intercept	Correlation Coefficient	N
serum				
0.15* - 22.00 mg/dL	1.01	-0.01	1.0	12
urine				
3.00* – 425.34 mg/dL	0.998	-0.41	1.0	12

*represents the LoQ

5.13 Analytical Specificity

5.13.1 Non-interfering Substances

CLSI EP7A2 was followed for the interference testing. The interference study was conducted using a "paired difference worst case scenario" approach where these compounds were spiked into fresh sample pools containing either low or high levels of creatinine analyte in both serum pools and urine pools.

DM CRE2	Serum/Plasma Substances						
		DM CRE2					
Substance	Concentration of Substance (mg/dL)	LOW pool (~ 1.5mg/dL)			HIGH pool (~ 5.0 mg/dL)		
		Mean	Control	% Diff	mean	control	% Diff
Acetaminophen	20	1.35	1.37	-2%	4.90	4.75	3%
Acetoacetate	20	1.43	1.43	0%	4.83	4.81	0%
Amikacin	8	1.39	1.37	1%	4.76	4.75	0%
Ampicillin	5.3	1.39	1.37	1%	4.72	4.75	-1%
Ascorbic Acid	6	1.41	1.39	2%	4.90	4.74	3%
Caffeine	6	1.38	1.37	1%	4.76	4.75	0%
Carbamazepine	3	1.39	1.39	0%	4.77	4.84	-1%
Cephalexin	25	1.46	1.43	2%	4.88	4.81	1%
Cephapirin	25	1.46	1.43	2%	4.86	4.87	0%
Cephradine	25	1.43	1.43	0%	4.88	4.87	0%
Chloramphenicol	5	1.41	1.36	3%	4.76	4.79	-1%
Chlordiazepoxide	1	1.37	1.38	-1%	4.79	4.72	1%
Chlorpromazine	0.2	1.36	1.37	-1%	4.77	4.70	1%
Cholesterol Supertrate	503	1.31	1.31	0%	4.42	4.35	2%
Cimetidine	2	1.37	1.37	0%	4.74	4.75	0%
Dextran 40	6000	1.55	1.49	4%	4.98	5.04	-1%
Diazepam	0.51	1.39	1.38	1%	4.76	4.72	1%
Digoxin	6.1ng/mL	1.42	1.41	0%	4.72	4.71	0%
EDTA	200	1.37	1.36	0%	4.86	4.80	1%
Erythromycin	6	1.38	1.36	1%	4.72	4.79	-1%
Ethanol	400	1.39	1.39	0%	4.77	4.74	0%
Ethosuximide	25	1.39	1.37	1%	4.74	4.75	0%
Furosemide	6	1.40	1.36	2%	4.77	4.79	0%
Gentamicin	1	1.38	1.39	0%	4.72	4.74	-1%
Heparin (196 Units/mg)	3 U/mL	1.38	1.37	1%	4.74	4.74	0%
Ibuprofen	50	1.41	1.39	2%	4.80	4.84	-1%
Immunoglobulin G (IgG)	5000	1.56	1.49	5%	5.07	5.04	1%
Isopropanol	1.0 g/dL	1.38	1.36	1%	4.81	4.80	0%
Lidocaine	1.2	1.39	1.36	2%	4.79	4.79	0%
Lithium	2.2	1.37	1.37	0%	4.73	4.70	0%
Nicotine	0.1	1.40	1.39	0%	4.82	4.84	0%
Nortriptyline	1000 ng/mL	1.40	1.36	2%	4.85	4.80	1%
Penicillin G (1654 Units/mg)	25 U/mL	1.37	1.37	0%	4.71	4.70	0%
Pentobarbital	8	1.41	1.37	3%	4.74	4.79	-1%
Phenobarbital	10	1.39	1.37	1%	4.79	4.79	0%
Phenytoin	5	1.38	1.38	0%	4.81	4.72	2%
Potassium oxalate	500 mg/dL	1.46	1.43	2%	4.90	4.81	2%
Primidone	4	1.40	1.39	1%	4.75	4.84	-2%
Propoxyphene	0.16	1.36	1.38	-2%	4.76	4.72	1%

DM CRE2	Serum/Plasma Substances						
		DM CRE2					
Substance	Concentration of Substance (mg/dL)	LOW pool (~ 1.5mg/dL)			HIGH pool (~ 5.0 mg/dL)		
		Mean	Control	% Diff	mean	control	% Diff
Protein, Albumin	6000	1.49	1.49	0%	4.73	5.20	-9%
Protein, Total	12g/dL	1.57	1.49	6%	4.95	4.98	-1%
Salicylic acid	60	1.41	1.36	4%	4.79	4.79	0%
Sodium fluoride	400	1.35	1.34	1%	4.59	4.59	0%
Theophylline	4	1.39	1.37	1%	4.83	4.75	2%
Urea	500	1.42	1.37	3%	4.80	4.70	2%
Uric acid	20	1.40	1.39	0%	4.98	4.77	4%
Valproic acid	50	1.38	1.37	1%	4.76	4.75	0%
Vancomycin	10	1.42	1.39	2%	4.81	4.74	1%

DM CRE2	Urine Substances						
		DM CRE2					
Substance	Concentration of Substance (mg/dL)	LOW pool (~40 mg/dL)			HIGH pool (~ 175 mg/dL)		
		Mean	Control	% Diff	mean	control	% Diff
50% Acetic Acid	25mL/24 hr collection	41.23	40.82	1%	180.56	178.44	1%
6N Hydrochloric Acid	0.6%	41.76	41.41	1%	180.84	181.20	0%
6N Nitric Acid	0.6%	41.95	41.41	1%	181.85	181.20	0%
Acetone	100 mg/dL	41.53	42.10	-1%	181.95	183.29	-1%
Bilirubin (conjugated)	2 mg/dL	41.39	41.05	1%	179.95	180.73	0%
Boric Acid	1% w/v	40.46	41.91	-3%	183.69	183.76	0%
Ethanol	1 g/dL	41.44	42.20	-2%	180.88	184.21	-2%
Gamma Globulin	0.5 g/dL	41.24	41.69	-1%	182.54	180.88	1%
Glucose	2 g/dL	41.06	41.69	-2%	178.55	180.88	-1%
Hemoglobin	115 mg/dL	42.09	41.93	0%	183.40	179.88	2%
Human Serum Albumin	0.5 g/dL	40.55	41.49	-2%	180.8	179.8	1%
Oxalic Acid	0.1 g/dL	39.94	39.50	1%	173.04	172.25	0%
Sodium Carbonate	5g/24 hr collection	41.26	40.74	1%	179.24	180.10	0%
Sodium Fluoride	1% w/v	41.65	41.91	-1%	184.79	183.76	1%

5.13.2 Interfering Substances

The CRE2 method was evaluated for interference according to CLSI EP7-A2. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference. Dilution studies were conducted to determine the level at which the spiked substance no longer displayed significant interference. These studies were conducted at

two Creatinine analyte concentrations, if both sample pools show significant interference. This study was conducted as needed for both serum pools and urine pools.

Substance	Concentration of Substance	Mean Test CRE2 Result (mg/dL)	Mean Control CRE2 Result (mg/dL)	%Diff
Serum/Plasma Sample Type				
Acetone	18.75 mg/dL	1.56	1.41	11%
Acetone	75 mg/dL	5.37	4.84	11%
Bilirubin (unconj)	20 mg/dL	1.20	1.50	-20.2%
Cefoxitin	5 mg/dL	1.62	1.43	13%
Cephalothin	12.5 mg/dL	1.57	1.41	12%
Glucose	500 mg/dL	1.60	1.43	12%
Intralipid 20%	1500 mg/dL	1.50	1.35	11.3%
Pyruvate	10.5 mg/dL	5.71	4.81	19%
Triglycerides	3000 mg/dL	1.42	1.22	16%
Urine Sample Type				
Ascorbic Acid	0.15 g/dL	44.29	39.97	11%
Ascorbic Acid	0.3 g/dL	199.52	178.25	12%

5.13.3 Hemolysis, Icterus, Lipemia (HIL) Interference

The CRE2 method was evaluated for interference according to CLSI EP7-A2. Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

DM CRE2	HIL Interference			
Substance	**Concentration of Substance (mg/dL)**	**Mean Test CRE2 Result (mg/dL)**	**Mean Control CRE2 Result (mg/dL)**	**% Difference**
Hemoglobin	1000	4.54	4.69	-3.2%
Hemoglobin	1000	1.24	1.4	-11.1%
Hemoglobin	500	1.37	1.44	-4.9%
Bilirubin (conj)	40	4.79	4.86	-1.3%
Bilirubin (conj)	40	1.16	1.40	-17.2%
Bilirubin (conj)	20	1.38	1.46	-5.5%
Bilirubin (unconj)	40	4.79	4.89	-2.0%
Bilirubin (unconj)	20	1.20	1.50	-20.2%
Bilirubin (unconj)	10	1.32	1.46	-9.6%
Intralipid 20%	2000	4.66	4.56	2.2%
Intralipid 20%	1500	1.50	1.35	11.3%
Intralipid 20%	1000	1.49	1.39	7.2%

5.14 Conclusion

The Dimension® Creatinine (CRE2) Flex® reagent cartridge (DF33B) is substantially equivalent in principle and performance to the Creatinine Method for Use on the Dimension® Clinical Chemistry System (CREA) cleared under k925668. Comparative testing described in the submission demonstrates substantially equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 27, 2014

SIEMENS HEALTHCARE DIAGNOSTICS INC.
LAURA DUGGAN, PH.D.
REGULATORY TECHNICAL SPECIALIST
P.O. BOX 6101
NEWARK DE 19714

Re: K132638
Trade/Device Name: Dimension® Creatinine (CRE2) Flex® reagent cartridge
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: II
Product Code: CGX
Dated: November 13, 2013
Received: November 14, 2013

Dear Dr. Duggan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
k132638

Device Name
Dimension® Creatinine (CRE2) Flex® reagent cartridge

Indications for Use *(Describe)*
The CRE2 method is an in vitro diagnostic test for the quantitative measurement of creatinine in human serum, plasma, and urine on the Dimension® clinical chemistry system. Creatinine measurements are used in the diagnosis and treatment of certain renal disease, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ruth A. Chesler -S